

(8) The rate of tax per cubic yard determined by the California Debris Commission applicable to the particular mine; and

(9) The amount of tax due and payable (cubic yards mined multiplied by the rate of tax per cubic yard).

(c) *Supporting statement.* With each return there must be submitted a supporting statement of the person who made the surveys at the mine for the mining season covered by the return (see §50.6), stating that such surveys were made in accordance with requirements prescribed by the California Debris Commission.

(d) *Verification of return and supporting statement.* The return and the supporting statement shall be verified by written declarations that they are made under the penalties of perjury.

§50.8 Due date and place for filing returns and paying tax.

The return for a taxable year shall be filed with, and the tax shall be paid to, the district director at San Francisco, California, on or before September 30 of the calendar year in which the taxable year ends. The tax is due and payable on such date without assessment by, or notice from, the district director.

PART 51—BRANDED PRESCRIPTION DRUG FEE

Sec.

51.1 Overview.

51.2 Explanation of terms.

51.2T Explanation of terms (temporary).

51.3 Information requested from covered entities.

51.4 Information provided by the agencies.

51.5 Fee calculation.

51.6 Notice of preliminary fee calculation.

51.7 Dispute resolution process.

51.8 Notification and payment of fee.

51.9 Tax treatment of fee.

51.10 Refund claims.

51.11 Effective/applicability date.

51.11T Effective/applicability date.

51.6302-1 Method of paying the branded prescription drug fee.

AUTHORITY: 26 U.S.C. 7805; sec. 9008, Public Law 111-347 (124 Stat. 119).

Section 51.8 also issued under 26 U.S.C. 6302(a).

Section 51.6302-1 also issued under 26 U.S.C. 6302(a).

SOURCE: T.D. 9544, 76 FR 51249, Aug. 18, 2011, unless otherwise noted.

§51.1 Overview.

(a) The regulations in this part 51 are designated “Branded Prescription Drug Fee Regulations.”

(b) The regulations in this part 51 provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111-152 (124 Stat. 1029 (2010)). All references in these regulations to section 9008 are references to section 9008 of the ACA, as amended by section 1404 of HCERA. Unless otherwise indicated, all other section references are to sections in the Internal Revenue Code. All references to “fee” in these regulations are references to the fee imposed by section 9008.

(c) Section 9008(b)(4) sets an applicable fee amount for each year, beginning with 2011, that will be apportioned among covered entities with aggregate branded prescription drug sales of over \$5 million to government programs or pursuant to coverage under such programs. Generally, each covered entity is liable for a fee in each fee year that is based on its sales of branded prescription drugs in the sales year that corresponds to the fee year in an amount determined by the Internal Revenue Service (IRS) under the rules of this part.

[T.D. 9684, 79 FR 43639, July 28, 2014]

§51.2 Explanation of terms.

(a) *In general.* This section explains the terms used in this part for purposes of the fee imposed by section 9008 on branded prescription drugs.

(b) *Agencies.* The term *Agencies* means—

(1) The Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS);

(2) The Department of Veterans Affairs (VA); and

(3) The Department of Defense (DOD).

(c) *Branded prescription drug—(1) In general.* The term *branded prescription drug* means—